General

Guideline Title

IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes.

Bibliographic Source(s)

Bus SA, van Netten JJ, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Price PE, International Working Group on the Diabetic Foot. IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):16-24. [68 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the International Working Group on the Diabetic Foot (IWGDF): For the 2015 IWGDF Guidance documents, the IWGDF invited five working groups of international experts to produce guidance on the prevention and management of foot problems in diabetes. Major recommendations provided in the *IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes* are presented below. See also the NGC summaries of IWGDF guidance on the following related topics:

- Footwear and offloading to prevent and heal foot ulcers in diabetes
- Diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers in diabetes
- Diagnosis and management of foot infections in persons with diabetes
- Interventions to enhance healing of chronic ulcers of the foot in diabetes

Definitions for the quality of the evidence (High, Moderate, Low, Very Low) and strength of recommendations (Strong, Weak) are provided at the end of the "Major Recommendations" field.

General Recommendations

Should a person with diabetes be screened for foot ulcer risk?

To identify a person with diabetes at risk for foot ulceration, examine the feet annually to seek

evidence for signs or symptoms of peripheral neuropathy and peripheral artery disease. (Grading of Recommendations Assessment, Development and Evaluation [GRADE] strength of recommendation: Strong; Quality of evidence: Low)

What should an at-risk person with diabetes be screened for?

In a person with diabetes who has peripheral neuropathy, screen for a history of foot ulceration or lower-extremity amputation, peripheral artery disease, foot deformity, pre-ulcerative signs on the foot, poor foot hygiene, and ill-fitting or inadequate footwear. (Strong; Low)

Is the treatment of a pre-ulcerative sign on the foot effective in preventing a foot ulcer in an at-risk patient with diabetes?

Treat any pre-ulcerative sign on the foot of a patient with diabetes. This includes removing callus, protecting blisters and draining when necessary, treating ingrown or thickened toe nails, treating hemorrhage when necessary and prescribing antifungal treatment for fungal infections. (Strong; Low)

What should an at-risk patient with diabetes avoid when walking at home or outside?

To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks only, or in thin-soled standard slippers, whether at home or when outside. (Strong; Low)

What self-management interventions should a patient perform on a regular basis?

Instruct an at-risk patient with diabetes to daily inspect their feet and the inside of their shoes, daily wash their feet (with careful drying particularly between the toes), avoid using chemical agents or plasters to remove callus or corns, use emollients to lubricate dry skin and cut toe nails straight across. (Weak; Low)

Is footwear effective in preventing a first or recurrent non-plantar foot ulcer in an at-risk patient with diabetes?

Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles or toe orthosis. (Strong; Low)

Is therapeutic footwear effective in preventing a recurrent plantar foot ulcer in at-risk patients with diabetes?

To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking (i.e., 30% relief compared with plantar pressure in standard of care therapeutic footwear) and encourage the patient to wear this footwear. (Strong; Moderate)

Is patient education effective in preventing a first foot ulcer in an at-risk patient?

To prevent a first foot ulcer in an at-risk patient with diabetes, provide education aimed at improving foot care knowledge and behavior, as well as encouraging the patient to adhere to this foot care advice. (Weak; Low)

Is integrated foot care effective in preventing recurrent foot ulcers in at-risk patients with diabetes?

To prevent a recurrent foot ulcer in an at-risk patient with diabetes, provide integrated foot care, which includes professional foot treatment, adequate footwear and education. This should be repeated or re-evaluated once every 1 to 3 months as necessary. (Strong; Low)

Is self-management of foot health effective in preventing a first or recurrent foot ulcer in at-risk patients with diabetes?

Instruct a high-risk patient with diabetes to monitor foot skin temperatures at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation. (Weak; Moderate)

Are surgical interventions effective in preventing a foot ulcer in at-risk patients?

Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the distal toe. (Weak; Low)
Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar forefoot ulcer. (Weak; Low)
Do not use a nerve decompression procedure in an effort to prevent a foot ulcer in an at-risk patient with diabetes, in preference to accepted standards of good quality care. (Weak; Low)

Definitions

Recommendations in the guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the quality of evidence on the risk of bias of included studies, effect sizes, and expert opinion, and rated the quality of evidence as 'high,' 'moderate' or 'low.' They assessed the strength of each recommendation as 'strong' or 'weak,' based on the quality of evidence, balance between benefits and harm, patient values and preferences, and costs (resource utilization). The rationale behind each recommendation is described in the original guideline document. See the GRADE Web site for more information.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Diabetic foot ulcers

Guideline Category

Prevention

Screening

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Podiatry

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Podiatrists

Guideline Objective(s)

To provide recommendations for prevention of foot ulcers in at-risk patients with diabetes

Target Population

Persons with type 1 or 2 diabetes mellitus who are at risk for foot ulceration

Interventions and Practices Considered

1. Annual foot examination for signs or symptoms of peripheral neuropathy and peripheral artery disease (PAD)
2. Screening for history of foot ulceration or lower-extremity amputation, PAD, foot deformity, pre-ulcerative signs on the foot, poor foot hygiene and ill-fitting or inadequate footwear
3. Treatment of pre-ulcerative signs
4. Patient education
    - Wearing of proper footwear inside and outside
    - Daily foot inspection and care
    - Monitoring of foot skin temperature
5. Prescription of therapeutic footwear
6. Integrated foot care (patient education and professional foot treatment)
7. Digital flexor tenotomy
8. Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, or osteotomy

Note: Nerve decompression is considered but not recommended.

Major Outcomes Considered

- First foot ulcer
- Recurrent foot ulcer

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

The systematic review for this guideline (see the "Availability of Companion Documents" field) was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic review was prospectively registered in the PROSPERO database for systematic reviews (CRD42014012964).

The population of interest for the systematic review was persons with type 1 or 2 diabetes mellitus who are at risk for foot ulceration. In accordance with the International Working Group on the Diabetic Foot (IWGDF) definition, 'at-risk' was defined as 'presence of peripheral neuropathy, with or without a foot deformity or peripheral artery disease, or a history of foot ulcer(s) or amputation of (a part of) the foot or leg'. Primary outcomes were first diabetic foot ulcer and recurrent diabetic foot ulcer. A diabetic foot ulcer was defined as a 'full thickness lesion of the skin distal to the malleoli in a person with diabetes mellitus'. 'First ulcer' was the first-ever recorded diabetic foot ulcer in a patient. 'Recurrent ulcer' was any foot ulcer after successful healing of a previous one, irrespective of which foot or at what location on the foot the ulcer recurred. The systematic review authors have reported first and recurrent ulcer separately because patients with a previous ulcer are considered at higher risk compared with those without, and consequently, these patients require more preventative foot care. If a study included both patients with and without a previous ulcer and results were not presented separately for first and recurrent ulcers, the primary outcome was 'first/recurrent ulcer'.

Original research studies were included that reported on interventions that had the goal to prevent a first or recurrent foot ulcer in the population of interest. The reviewers defined three groups of interventions *a priori* and systematically reviewed the literature for each group separately in order to structure the literature search and to distribute assignments among reviewers.

> Care: interventions aimed at improvements in care, such as with podiatry, chiropody, multidisciplinary care, integrated foot care, screening interventions to detect and treat patients at risk for diabetic foot ulceration, or interventions aimed at education of health care professionals.
> Self-management: interventions aimed at the self-management of patients, such as patient education, home monitoring of foot status, or lifestyle interventions.
> Medical: generally hospital-based interventions, such as surgery and therapeutic footwear.

The reviewers excluded studies on healthy subjects, on persons with diseases other than diabetes or on persons with diabetes who are not at risk for foot ulceration. They only included studies of persons with active ulcers when these studies reported outcomes on ulcer recurrence after healing of the active ulcer. They excluded studies on interventions with surrogate outcomes related to ulcer prevention, for example, studies with results on foot care behavior, knowledge, and awareness, quality of life, pre-ulcerative lesions, plantar pressure or amputation only. They included systematic reviews and meta-analyses, randomized controlled trials, non-randomized controlled trials, case–control studies, cohort studies, (controlled) before-and-after studies, interrupted time series, prospective and retrospective non-controlled studies, cross-sectional studies and case series. They excluded case reports.

Before performing the systematic search of the literature, reviewers created validation sets of approximately 20 publications for each group of interventions. Each publication in the sets had to be identified in the literature search. The validation set was created by first including key publications known to the authors that fit the scope of this systematic review. Secondly, reference lists in these publications and references to these publications were checked and key publications were included in the validation set. Finally, the World Health Organization International Clinical Trials Registry Platform (WHO-ICTRP) (http://apps.who.int/trialsearch/default.aspx) was searched using the search string (Diabet* AND ulcer* OR diabet* AND reulcer* OR diabet* AND amput). The reviewers screened identified trials for relevance in relation to the scope of the systematic review and searched trial numbers and authors of relevant trials in PubMed to identify publications to be added to the validation set.

The literature search was performed on 24 July 2014, covered publications in all languages and was not restricted by date. The following databases were searched: PubMed, Excerpta Medica Database (EMBASE) via Ovid SP, Cumulative Index to Nursing & Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Reviews of Effect and Cochrane Central Register of Controlled Trials. The search strings (see online Appendix 1–4 of the systematic review) for each database were prepared with the help of a clinical librarian.

For each of the three groups of interventions, two members of the working group independently reviewed publications by title and abstract for eligibility to be included in the analysis, based on four criteria: population; study design; outcomes; and intervention. Cohen's kappa was calculated for agreement between reviewers. Reviewers discussed and reached consensus on any disagreement on inclusion of publications. Publications identified in more than one intervention group were discussed between all reviewers and further analysed within the intervention group for which the study best fitted. Subsequently, the same two reviewers independently assessed full-paper copies of included publications on the same four criteria for final eligibility. Conference proceedings, if included after assessment of title and abstract, were used to search for full-paper publications. If no full-paper copy of the study was found, the authors were contacted for more information, to assess for any possible publication bias or selective reporting of results. Tracking of references of included publications was not performed.

To further assess for possible publication bias or selective reporting of results, the WHO-ICTRP trial registry (http://apps.who.int/trialsearch/default.aspx) was searched on 30 July 2014. The Clinicaltrials.gov registry was also searched separately (https://clinicaltrials.gov) on 31 July 2014 (see online Appendix 5 of the systematic review). Two reviewers independently assessed identified trials for eligibility based on three criteria: patient group; outcomes; and intervention. Reviewers retrieved the status of eligible trials ('completed', 'ongoing' or 'not yet started') from the databases. Cohen's kappa was calculated for agreement. Reviewers solved disagreement concerning eligibility by discussion, until consensus was reached. Any relevant publication related to a completed trial was searched for in the same databases as for the literature search. If no publications were identified, the principal investigator of the trial was contacted for more information.

Number of Source Documents

The literature database search identified a total of 3061 publications for intervention group 1 (care), 2641 publications for group 2 (self-management) and 2793 publications for group 3 (medical), and identified 556 trials in the trial registries search (see Figure 1 in the systematic review [see the "Availability of Companion Documents" field]). Contacting authors of conference proceedings did not result in the addition of any publications. A total of 74 publications were included for qualitative analysis, of which 30 were controlled studies (19 randomized controlled trials [RCTs] and 11 nonrandomized controlled studies).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Recommendations in the guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the quality of evidence on the risk of bias of included studies, effect sizes, and expert opinion, and rated the quality of evidence as 'high', 'moderate' or 'low'. See the GRADE Web site for more information.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The authors of the systematic review (see the "Availability of Companion Documents" field) used the Scottish Intercollegiate Grouping Network (SIGN) algorithm for classifying study design for questions of effectiveness (http://www.sign.ac.uk/pdf/studydesign.pdf) to classify the study design for each publication. The same two reviewers per intervention group independently assessed included publications with a controlled study design for methodological quality (i.e., risk of bias), using scoring sheets developed by the Dutch Cochrane Centre (www.cochrane.nl). Reviewers resolved disagreement regarding risk of bias by discussion, until consensus was reached. The SIGN level of evidence was determined for each publication. Level 1 refers to randomized controlled trials and Level 2 refers to case–control, cohort, controlled before-and-after designs or interrupted time series. Risk of bias was scored for each study as ++ (very low risk of bias), + (low risk of bias) or – (high risk of bias). Data were extracted from each included publication with a controlled study design and summarized in the evidence table. This table included patient and study characteristics, characteristics of the intervention and control conditions and primary and secondary outcomes. One of the reviewers extracted the data; the other reviewer checked this for content and presentation. All members of the working group thoroughly discussed the evidence table. Reviewers did not participate in the assessment, data extraction and discussion of publications of which they were a co-author, to prevent any conflict of interest.

Finally, the two reviewers per group drew conclusions for each intervention based on the strength of the available evidence. All members of the working group discussed these conclusions, until consensus was reached.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Following the systematic review, the experts in the working group formulated recommendations based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The GRADE system allows the experts to provide a rating for each recommendation based on both the strength with which it is recommended and the quality of the evidence underlying it. In this manner the link is made between scientific evidence and recommendations for daily clinical practice (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Recommendations in the guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the strength of each recommendation as 'strong' or 'weak', based on the quality of evidence, balance between benefits and harm, patient values and preferences, and costs (resource utilization). See the GRADE Web site for more information.

Cost Analysis

Costs and cost-effectiveness have not been investigated for any of the interventions described in this guidance, and more attention to cost aspects is warranted.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Consensus

The members of the International Working Group on the Diabetic Foot (IWGDF) Editorial Board met in person on a number of occasions to thoroughly review the systematic reviews and the guidance documents, which were then revised by the working group based on this editorial review. When found satisfactory, the Editorial Board sent the guidance document to the IWGDF representatives for comments; the editorial board processed all comments received and made changes where needed in collaboration with the chair of the working group.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Foot ulcers are a major complication of diabetes mellitus, with high morbidity, mortality and costs. Yearly incidence is estimated to be around 2%, but this increases substantially when patients successfully heal from a foot ulcer, with reported recurrence rates between 30% and 40% in the first year. Prevention of these ulcers is of paramount importance to reduce the patient and economic burden.
- The aim of more frequent screening is early identification of factors that can increase the chances of developing a foot ulcer, followed by providing appropriate preventative foot care. For example, early diagnosis and treatment of pre-ulcerative signs on the foot may prevent foot ulcers, as well as more severe complications such as infection and hospitalization.

Refer to the "Rationale" sections in the original guideline document for an assessment of balance of benefits and harms for each recommendation.

Potential Harms

- Adherence to self-management was an important factor in the conducted randomized controlled trials, and patients, in particular those who have not had a foot ulcer, may find the requirement for daily assessment a burden. False-positive and false-negative outcomes of temperature measurements may unnecessarily concern or stress patients and affect their confidence in this approach.
- Possible complications and side effects of surgical offloading techniques include post-operative infection, new deformities, gait problems and transfer ulcers. Clinicians should carefully discuss possible adverse effects of the surgery with the patient.

- The possible benefits of digital flexor tenotomy likely outweigh the harm, as few complications have been reported. Possible adverse effects of the surgery, although minimal, should be discussed with the patient.

Refer to the "Rationale" sections in the original guideline document for an assessment of balance of benefits and harms for each recommendation.

Qualifying Statements

Qualifying Statements

Qualifying Statements

Not stated

Implementation of the Guideline

Description of Implementation Strategy

Guidelines will be implemented via the training programs of the International Working Group on the Diabetic Foot (IWGDF) as well as with support of the translation of the guidelines in local languages.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Bus SA, van Netten JJ, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Price PE, International Working Group on the Diabetic Foot. IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):16-24. [68 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Jan

Guideline Developer(s)

International Working Group on the Diabetic Foot - Nonprofit Organization

Source(s) of Funding

International Working Group on the Diabetic Foot

Guideline Committee

International Working Group on the Diabetic Foot

Composition of Group That Authored the Guideline

Authors: S. A. Bus, Department of Rehabilitation Medicine, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; J. J. van Netten, Diabetic Foot Clinic, Department of Surgery, Ziekenhuisgroep Twente, Almelo and Hengelo, the Netherlands; L. A. Lavery, Department of Plastic Surgery, University of Texas Southwestern Medical Center, Dallas, TX, USA; M. Monteiro-Soares, CIDES/CINTESIS – Health Information and Decision Sciences Department (U753-FCT), Faculty of Medicine of the University of Porto, Oporto, Portugal; A. Rasmussen, Steno Diabetes Center A/S, Gentofte, Denmark; Y. Jubiz, Diabetic Foot Unit, Colombian Diabetes Association, Bogotá, Colombia; P. E. Price, Vice Chancellors' Office, Cardiff University, Cardiff, Wales, UK

Financial Disclosures/Conflicts of Interest

The International Working Group on the Diabetic Foot Guidance is developed by working groups of independent experts. These documents are written without any influence from commercial, political, academic or other interest groups.

Conflicts of Interest

LL is on the speaker's bureau for Osiris, Integra, PamLabs and Smit & Nephew, a consultant for KCI, PamLabs and Innovacyn, a stock owner in Prizm Medical and received research grants from Osiris, MacroCure, ThermoTrek, Integra, GlaxoSmithKline, KCI, Cardinal and Dipexium. SB, JvN, AR, MMS, YJ and PP have no conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Diabetes/Metabolism Research and Reviews Web site .

Availability of Companion Documents

The following is available:

Van Netten JJ, Price PE, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Bus SA, International Working Group on the Diabetic Foot (IWGDF). Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):84-98. Available from the Diabetes/Metabolism Research and Reviews Web site .

Bakker K, Apvelqvist J, Lipsky BA, Van Netten JJ, Schaper NC, International Working Group on the Diabetic Foot (IWGDF). The 2015 IWGDF guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):2-6. Available from the Diabetes/Metabolism Research and Reviews Web site .

Schaper NC, Van Netten JJ, Apelqvist J, Lipsky BA, Bakker K, International Working Group on the Diabetic Foot (IWGDF). Prevention and management of foot problems in diabetes: a summary guidance for daily practice 2015, based on the IWGDF Guidance Documents. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):7-15. Available from the Diabetes/Metabolism Research and Reviews Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 4, 2016. The information was verified by the guideline developer on December 11, 2016.

Copyright Statement

Disclaimer

NGC Disclaimer

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.